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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
| 10/557,991 | 11/22/2005 | Paul James Davis | 056222-5094 | 5135 |
| 9629 7590 07/22/2009 MORGAN LEWIS & BOCKIUS LLP 1111 PENNSYLVANIA AVENUE NW WASHINGTON, DC 20004 | | | | |
| EXAMINER | | | | |
| UNDERDAHL, THANE E | | | | |
| ART UNIT | | PAPER NUMBER | | |
| 1651 | | | | |
| MAIL DATE | | DELIVERY MODE | | |
| 07/22/2009 | | PAPER | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/557,991

Applicant(s)

DAVIS ET AL.

Examiner

THANE UNDERDAHL

Art Unit

1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 July 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 and 11-17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9 and 11-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/5508)
Paper No(s)/Mail Date 7/10/09
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

Detailed Action

This Office Action is in response to the Applicant's reply received 6/3/09. Claims 1-9, 11-17 are pending. No Claims are withdrawn. Claims 10, 18-26 are cancelled. Claims 1 has been amended. No Claims are new. Claims 1-9 and 11-17 are considered in this Office Action.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 6/3/09 has been entered.

Response to Applicant's Arguments

In the response submitted by the Applicant:

- the 35 U.S.C § 102 (b) rejection of claims 1, 2, 4, 5, 8, 9 and 11 based on Sakai et al. is withdrawn in light of Applicant's amendment that the composition is an irradiated mixture.
- The 35 U.S.C § 103 (a) rejection of claims 1-9 and 11 based on Sakai et al. alone is withdrawn in light of Applicant's amendment

- o The 35 U.S.C § 103 (a) rejection of claims 1-9 and 11-17 based on Sakai et al. in view of Green is withdrawn in light of Applicant's amendment.

New Rejections Necessitated by Amendment

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 11 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 11 recites the limitation "sterilizing radiation". There is insufficient antecedent basis for this limitation in the claim after the amendment to claim 1.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 4-5, 8, 9, 11 and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Hersh et al. (U.S. Patent # 6337320, 2002) in light of Gamma Rays in Our Atmosphere (1997).

The Applicant is reminded that a 35 U.S.C. 102 rejection over multiple references has been held to be proper when the extra references are cited to (M.P.E.P. § 2131.01):

(C) Show that a characteristic not disclosed in the reference is inherent.

These claims are to a composition that comprises an irradiated mixture of:

- Enzyme
- Source of lactate ions
- A source of zinc ions and/or ammonium ions

The ions are sufficient to maintain activity of the enzyme.

The Examiner acknowledges that the amendment changing the composition from "subjected to sterilizing irradiation" to "comprising an irradiated mixture" removes the product-by-process language previously interpreted by the Examiner. However these claims do not limit the degree of irradiation or the type of irradiation. Furthermore the limitation that the composition be sterilized is removed by the current amendments. Therefore the broad interpretation of the claims reads on any irradiation by any EM source (i.e. UV, IR and visible light as well as radio waves) to any degree. Also the claims do not indicate the structural consequence of the irradiation or more specifically how the composition is changed by the irradiation.

Hersh et al. teach a sunscreen composition (Example 8) that comprises:

- Water (for the enzyme to be in a wet active state)
- Zinc glycopeptides (source capable of releasing zinc)
- Sodium lactate (source capable of releasing lactate)
- **Superoxide dismutase (SOD)**
- Epidermal growth factor (a protein)
- Hydroxyethylcellulose (neutral water soluble polymer).

Once the sunscreen is applied to the skin it is inherently irradiated by UV-visible light radiation by the sun as well as some gamma radiation as supported by Gamma Rays in Our Atmosphere (The Answer, Pg 1). The SOD actively removes free oxygen radical on the skin surface (col 20, lines 47-55).

Therefore the references anticipate claims 1, 2, 4-5, 8, 9, 11 and 16.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 2, 4-8, 9, 11, 12, 14 and 16 rejected under 35 U.S.C. 103(a) as being unpatentable over Hersh et al. as applied to 1, 2, 4-5, 8, 9, 11 and 16 above and for the following rational.

While Hersh et al. does teach catalase (col 4, lines 45-50), xanthine oxidase (col 4, line 65), zinc salts (col 21, lines 22-35), can be added to their composition as well as lactate ions (Example 8) they do not specifically teach the salt zinc lactate. However, one of ordinary skill in the art would recognize that metal salts and the salts of organic acids rapidly dissolve in water and exist in the composition as dissociated ions. Therefore it would have been obvious to someone skilled in the art to add zinc lactate to they composition of Hersh et al. since they already have zinc ions and lactate ions from other salts in their composition and in an aqueous solution these salts would be art

recognized equivalents for the same purpose (M.P.E.P. § 2144.06 and 2144.07) since they both dissociate into the same ions.

Furthermore while Hersh et al. does not specifically teach that the lactate used is L-lactate this would be obvious to one of ordinary skill in the art. It is well known in the art that L-lactate is the only bioactive isomer of lactate. Since Hersh et al. teaches a pharmaceutical composition for administration to a human and already contains other L-isomers it would be obvious to use the bioactive isomer L-lactate in the composition since this is the simple substitution of one known bioactive element for one that has no bioactivity in a pharmaceutical composition (KSR International Co. v. Teleflex Inc., 550 U.S.--, 82 USPQ2d 1385 (2007)). Therefore the references listed above renders obvious claims 1, 2, 4-8, 9, 11, 12, 14 and 16.

Claims 1-9 and 11, 12, 14, 15, 16 rejected under 35 U.S.C. 103(a) as being unpatentable over Hersh et al. as applied to 1, 2, 4-8, 9, 11, 14 and 16 above and in view of Sauermann et al. (DE 19757826, 1999, Translated Abstract provided on Last page) or Terren et al. (U.S. Patent # 6231839, 2001).

Claims 3 and 15 limit that source of ammonium ions to ammonium sulphate or ammonium AMPS.

However ammonium sulfate is a common additives to sunscreens as taught by Sauermann et al. (see Translated Abstract on last page). Likewise Terren et al. teach that ammonium AMPS is also a common additive to sunscreen (col 1, lines 25-30 and col 5, lines 25-30) M.P.E.P. § 2144.06 states

"It is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art."

Therefore it is *prima facie* obvious to one of ordinary skill in the art to add more ammonium sulphate or ammonium AMPS to the composition of Hersh et al. since Sauermann et al. and Terren et al. teach that this is a known additive to sunscreens.

Therefore claims 1-9 and 11, 12, 14, 15, 16 are obvious in view of the above references.

Claims 1, 2, 4-9 and 11-14, 16 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hersh et al. as applied to 1, 2, 4-8, 9, 11, 12, 14 and 16 above and in view of Ribier et al. (U.S. Patent # 5741518, 1998).

Claim 13 limits the oxidase to glucose oxidase. Claim 17 limits the enzyme to lactoperoxidase. While Hersh et al. teach a sunscreen with SOD they do not teach glucose oxidase or lactoperoxidase. Regardless this would be obvious to one of ordinary skill in the art by the time the invention was made in view of the teachings of Ribier et al. who teach a sunscreens that can contain radical scavengers like SOD as well as glucose oxidase and lactoperoxidase (Ribier, col 6, Table I). M.P.E.P. § 2144.06 states

"It is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art."

Therefore it is *prima facie* obvious to one of ordinary skill in the art to add more glucose oxidase or lactoperoxidase with SOD in the composition of Hersh et al. since Ribier et al. teach that these enzymes are known additive to sunscreens.

Therefore claims 1, 2, 4-9 and 11-14, 16 and 17 are obvious in view of the above references.

No claims are currently allowed in this application.

In response to this office action the applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP § 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 U.S.C. § 102 or 35 U.S.C. § 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is requested to provide a list of all copending U.S. applications that set forth similar subject matter to the present claims. A copy of such copending claims is requested in response to this Office action.

CONTACT INFORMATION

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thane Underdahl whose telephone number is (571)

272-9042. The examiner can normally be reached Monday through Thursday, 8:00 to 17:00 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached at (571) 272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Thane Underdahl
Art Unit 1651

/Leon B Lankford/
Primary Examiner, Art Unit 1651